

EDITORIAL INDEX

IDENTIFICATION CODES

c—Cited
cd—Clinical dialogue
ed—Editorial
efm—EFM today
et—Equal time
F87—Fertility 1987

mu—Malpractice update
nl—News from the literature
oa—Original article
pd—Pediatric consultation
ppc—Problem-patient conference

pr—Protocol
s—Symposium
S87—Update on Surgery 1987
T88—Technology 1988
uc—Ultrasound clinic

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BACTERICIDAL

Macrodrantin® (nitrofurantoin macrocrystals)

50 mg
Capsules

Before prescribing or administering, see package circular for full product information. The following is a brief summary: **NOTE:** Specimens for culture and susceptibility testing should be obtained prior to and during drug administration. **INDICATIONS AND USAGE:** Macrodrantin is specifically indicated for the treatment of urinary tract infections when due to susceptible strains of *E. coli*, enterococci, *S. aureus* (it is not indicated for the treatment of associated renal cortical or perinephric abscesses), and certain susceptible strains of *Klebsiella*, *Enterobacter*, and *Proteus* species. **CONTRAINDICATIONS:** Anuria, oliguria, or significant impairment of renal function (creatinine clearance under 40 ml per minute) are contraindications. Treatment of this type of patient carries an increased risk of toxicity and is much less effective because of impaired excretion of the drug. The drug is contraindicated in pregnant patients at term (during labor and delivery) as well as in infants under one month of age because of the possibility of hemolytic anemia in the fetus or in the newborn infant due to immature erythrocyte enzyme systems (glutathione instability). Macrodrantin is also contraindicated in those patients with known hypersensitivity to nitrofurantoin. **WARNINGS:** Acute, subacute, or chronic pulmonary reactions have been observed in patients treated with nitrofurantoin. If these reactions occur, Macrodrantin should be discontinued and appropriate measures taken. Pulmonary reactions (diffuse interstitial pneumonitis or pulmonary fibrosis, or both) can develop insidiously, therefore close monitoring of patients on long-term therapy is warranted. Isolated reports have cited pulmonary reactions as a contributing cause of death. (See Respiratory reactions.) Hepatitis, including chronic active hepatitis, occurs rarely. Fatalities have been reported. The onset of chronic active hepatitis may be insidious, and patients receiving long-term therapy should be monitored periodically for changes in liver function. If hepatitis occurs, the drug should be withdrawn immediately and appropriate measures taken. Peripheral neuropathy, which may become severe or irreversible, has occurred. Fatalities have been reported. Conditions such as renal impairment (creatinine clearance under 40 ml per minute), anemia, diabetes mellitus, electrolyte imbalance, vitamin B deficiency, and debilitating disease may enhance the occurrence of peripheral neuropathy. Cases of hemolytic anemia of the primaquine sensitivity type have been induced by nitrofurantoin. Hemolysis appears to be linked to a glucose-6-phosphate dehydrogenase deficiency in the red blood cells of the affected patients. This deficiency is found in 10 percent of Negroes and a small percentage of ethnic groups of Mediterranean and Near-Eastern origin. Hemolysis is an indication for discontinuing Macrodrantin; hemolysis ceases when the drug is withdrawn. **PRECAUTIONS:** **Drug Interactions:** Magnesium trisilicate, when administered concomitantly with Macrodrantin, reduces both the rate and extent of absorption. The mechanism for this interaction probably is adsorption of drug onto the surface of magnesium trisilicate. Uricosuric drugs such as probenecid and sulfinpyrazone may inhibit renal tubular secretion of Macrodrantin. The resulting increase in serum levels may increase toxicity and the decreased urinary levels could lessen its efficacy as a urinary tract antibacterial. **Carcinogenesis, Mutagenesis:** Nitrofurantoin, when fed to female Holtzman rats at levels of 0.3% in a commercial diet for up to 44.5 weeks, was not carcinogenic. Nitrofurantoin was not carcinogenic when female Sprague-Dawley rats were fed a commercial diet with nitrofurantoin levels at 0.1% to 0.167% (total cumulative, 9.25 g) for 75 weeks. Further studies of the effects of chronic administration to rodents are in progress. Results of microbial *in vitro* tests using *Escherichia coli*, *Salmonella typhimurium*, and *Aspergillus nidulans* suggest that nitrofurantoin is a weak mutagen. Results of a dominant lethal assay in the mouse were negative. **Impairment of Fertility:** The administration of high doses of nitrofurantoin to rats causes temporary spermatogenic arrest; this is reversible on discontinuing the drug. Doses of 10 mg/kg or greater in healthy human males may, in certain unpredictable instances, produce slight to moderate spermatogenic arrest with a decrease in sperm count. **Pregnancy:** The safety of Macrodrantin during pregnancy and lactation has not been established. Use of this drug in women of childbearing potential requires that the anticipated benefit be weighed against the possible risks. **Labor and Delivery:** See CONTRAINDICATIONS. **Nursing Mothers:** Nitrofurantoin has been detected in breast milk, in trace amounts. Caution should be exercised when Macrodrantin is administered to a nursing woman, especially if the infant is known or suspected to have a glucose-6-phosphate dehydrogenase deficiency. **Pediatric Use:** Contraindicated in infants under one month of age. (See CONTRAINDICATIONS.) **ADVERSE REACTIONS:** **Gastrointestinal:** Hepatitis, including chronic active hepatitis, and cholestatic jaundice occur rarely. Nausea, emesis, and anorexia occur most often. Abdominal pain and diarrhea are less common gastrointestinal reactions. These dose-related reactions can be minimized by reduction of dosage. **Respiratory:** Chronic, subacute, or acute pulmonary hypersensitivity reactions may occur. Chronic pulmonary reactions are more likely to occur in patients who have received continuous treatment for six months or longer. Malaise, dyspnea on exertion, cough, and altered pulmonary function are common manifestations which can occur insidiously. Radiologic and histologic findings of diffuse interstitial pneumonitis or fibrosis, or both, are also common manifestations of the chronic pulmonary reaction. Fever is rarely prominent. The severity of chronic pulmonary reactions and their degree of resolution appear to be related to the duration of therapy after the first clinical signs appear. Pulmonary function may be impaired permanently, even after cessation of therapy. The risk is greater when chronic pulmonary reactions are not recognized early in subacute pulmonary reactions; fever and eosinophilia occur less often than in the acute form. Upon cessation of therapy, recovery may require several months. If the symptoms are not recognized as being drug-related and nitrofurantoin therapy is not stopped, the symptoms may become more severe. Acute pulmonary reactions are commonly manifested by fever, chills, cough, chest pain, dyspnea, pulmonary infiltration with consolidation or pleural effusion on x-ray, and eosinophilia. Acute reactions usually occur within the first week of treatment and are reversible with cessation of therapy. Resolution often is dramatic. **Neurologic:** Peripheral neuropathy, which may become severe or irreversible, has occurred. Fatalities have been reported. Conditions such as renal impairment (creatinine clearance under 40 ml per minute), anemia, diabetes mellitus, electrolyte imbalance, vitamin B deficiency, and debilitating diseases may increase the possibility of peripheral neuropathy. Less frequent reactions, of unknown causal relationship, are nystagmus, dizziness, headache, and drowsiness. **Dermatologic:** Exfoliative dermatitis and erythema multiforme (including Stevens-Johnson Syndrome) have been reported rarely. Transient alopecia also has been reported. **Allergic Reactions:** Lupus-like syndrome associated with pulmonary reaction to nitrofurantoin has been reported. Also, angioedema, maculopapular, erythematous or eczematous eruptions, urticaria, rash, and pruritus have occurred. Anaphylaxis, sialadenitis, pancreatitis, arthralgia, myalgia, drug fever, and chills or chills and fever have been reported. **Hematologic:** Agranulocytosis, leukopenia, granulocytopenia, hemolytic anemia, thrombocytopenia, glucose-6-phosphate dehydrogenase deficiency anemia, megaloblastic anemia, and eosinophilia have occurred. Cessation of therapy has returned the blood picture to normal. Aplastic anemia has been reported rarely. **Miscellaneous:** As with other antimicrobial agents, superinfections by resistant organisms, e.g., *Pseudomonas*, may occur. However, these are limited to the genitourinary tract because suppression of normal bacterial flora does not occur elsewhere in the body. **OVERDOSAGE:** Occasional incidents of acute overdosage of Macrodrantin have not resulted in any specific symptoms other than vomiting. In case vomiting does not occur soon after an excessive dose, induction of emesis is recommended. There is no specific antidote, but a high fluid intake should be maintained to promote urinary excretion of the drug. **DOSE AND ADMINISTRATION:** Macrodrantin should be given with food to improve drug absorption and, in some patients, tolerance. **Adults:** 50-100 mg four times a day—the lower dosage level is recommended for uncomplicated urinary tract infections. **Children:** 5-7 mg/kg of body weight per 24 hours, given in four divided doses (contraindicated under one month of age). Therapy should be continued for one week or for at least 3 days after sterility of the urine is obtained. Continued infection indicates the need for reevaluation. For long-term suppressive therapy in adults, a reduction of dosage to 50-100 mg at bedtime may be adequate. See WARNINGS section regarding risks associated with long-term therapy. For long-term suppressive therapy in children, doses as low as 1 mg/kg per 24 hours, given in a single or in two divided doses, may be adequate. Address medical inquiries to Norwich Eaton Pharmaceuticals, Inc., Medical Department, P.O. Box 191, Norwich, NY 13815-0191.

Manufactured by **Eaton Laboratories, Inc.**, Manati, Puerto Rico 00701
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MONISTAT® 7 Vaginal Cream
(miconazole nitrate 2%)

MONISTAT 7 Vaginal Suppositories
(miconazole nitrate, 100 mg)

MONISTAT 3 Vaginal Suppositories
(miconazole nitrate, 200 mg)

INDICATIONS AND USAGE: MONISTAT 7 Vaginal Cream, MONISTAT 7 Vaginal Suppositories and MONISTAT 3 Vaginal Suppositories are indicated for the local treatment of vulvovaginal candidiasis (moniliasis). MONISTAT 7 Vaginal Cream is effective in both pregnant and non-pregnant women, as well as in women taking oral contraceptives. Effectiveness in pregnancy has not been established for MONISTAT 7 Vaginal Suppositories or MONISTAT 3 Vaginal Suppositories. Effectiveness in diabetic patients has not been established for MONISTAT 3 Vaginal Suppositories.

CONTRAINDICATIONS: Patients known to be hypersensitive to this drug.

PRECAUTIONS: MONISTAT 7 Vaginal Cream, MONISTAT 7 Vaginal Suppositories, and MONISTAT 3 Vaginal Suppositories—General: Discontinue drug if sensitization or irritation is reported during use.

MONISTAT 7 Vaginal Suppositories and MONISTAT 3 Vaginal Suppositories—The base contained in the suppository formulation may interact with certain latex products, such as that used in vaginal contraceptive diaphragms. Concurrent use is not recommended.

MONISTAT 7 Vaginal Cream, MONISTAT 7 Vaginal Suppositories and MONISTAT 3 Vaginal Suppositories—Laboratory Tests: If there is a lack of response to MONISTAT, appropriate microbiological studies (standard KOH smear and/or cultures) should be repeated to confirm the diagnosis and rule out other pathogens.

MONISTAT 7 Vaginal Suppositories and MONISTAT 3 Vaginal Suppositories—Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term animal studies to determine carcinogenic potential have not been performed.

MONISTAT 7 Vaginal Suppositories and MONISTAT 3 Vaginal Suppositories—Fertility (Reproduction): Oral administration of miconazole nitrate in rats has been reported to produce prolonged gestation. However, this effect was not observed in oral rabbit studies. In addition, signs of fetal and embryotoxicity were reported in rat and rabbit studies and dystocia in rat studies after oral doses at and above 80 mg per kg. Intravaginal administration did not produce these effects in rats.

MONISTAT 7 Vaginal Cream, MONISTAT 7 Vaginal Suppositories, and MONISTAT 3 Vaginal Suppositories—Pregnancy: Since imidazoles are absorbed in small amounts from the human vagina, they should not be used in the first trimester of pregnancy unless the physician considers it essential to the welfare of the patient.

MONISTAT 7 Vaginal Suppositories and MONISTAT 3 Vaginal Suppositories—Nursing Mothers: It is not known whether miconazole nitrate is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when miconazole nitrate is administered to a nursing woman.

ADVERSE REACTIONS: MONISTAT 7 Vaginal Cream—During clinical studies with miconazole nitrate cream for a 14-day regimen, 39 of the 528 patients (7.4%) treated with miconazole nitrate cream reported complaints during therapy that were possibly drug-related. Most complaints were reported during the first week of therapy. Vulvovaginal burning, itching or irritation occurred in 6.6%, while other complaints such as vaginal burning, pelvic cramps, hives, skin rash and headache occurred rarely (each less than 0.2% patient incidence). The therapy-related dropout rate was 0.9%.

MONISTAT 7 Vaginal Suppositories—During clinical studies with regimens which varied from 1 to 14 days, 1,057 patients were treated with miconazole nitrate suppositories. The incidence of vulvovaginal burning, itching or irritation was 0.5%, while complaints of skin rash occurred at only a 0.2% incidence.

MONISTAT 3 Vaginal Suppositories—During clinical studies with the MONISTAT 3 Vaginal Suppository (miconazole nitrate, 200 mg) 301 patients were treated. The incidence of vulvovaginal burning, itching or irritation was 2%. Complaints of cramping (2%) and headaches (1.3%) were also reported. Other complaints (hives, skin rash) occurred with less than a 0.5% incidence. The therapy-related dropout rate was 0.3%.

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